



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

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Washington, D.C. 20231

12D

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/328,877 06/09/99 GURNEY

M 6142.N2-CP

HM12/0926

PHARMACIA & UPJOHN COMPANY
GLOBAL INTELLECTUAL PROPERTY
301 HENRIETTA STREET
KALAMAZOO MI 49001

EXAMINER

TURNER, S

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

09/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/328,877

Applicant(s)

Gurney et al.

Examiner
Sharon L. Turner, Ph.D.

Group Art Unit
1647



☒ Responsive to communication(s) filed on 1-18-00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-41 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-41 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to comply with Sequence Rules

☒ Attached Sequence Error Report.

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-23 and 34-38, drawn to polynucleotides, classified in class 536, subclass 23.1.
 - II. Claims 24-32, drawn to polypeptides, classified in class 530, subclass 350.
 - III. Claim 33, drawn to antibodies, classified in class 530, subclass 387.1.
 - IV. Claims 39-41, drawn to a method of identifying an agent, classified in class 436, subclass 518.
2. The inventions are distinct, each from the other because of the following reasons:
3. Groups I-III are related as products. The products are different each from the other as they are comprised of different structural and functional features including nucleic acids, amino acids, heavy and light chains and are capable of hybridization, acting as an immunogen and directing an immune response.
4. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the cell line can be practiced with

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Alzheimer's brain tissue and the cell line can be used in the process of producing alternative fusion polypeptides via transfection of nucleic acid vectors.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and the search required for each of the groups is not required for any other group, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species of the claimed invention: hhsel-10 polynucleotides and polypeptides and hmsel-10 polynucleotides and polypeptides.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 19, 21, 24, 32, 34 and 39 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

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limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to, Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 7:30-6:00 P.M.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
September 25, 2000

Patricia A. Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

09/328,877

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER

Please find below a communication from the EXAMINER in charge of this application

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given ONE MONTH from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Turner whose telephone number is (703) 308-0056. If the examiner cannot be reached, inquiries can be directed to Supervisory Patent Examiner Gary Kunz whose telephone number is (703) 308-4623. The fax number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☒ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: see attached error report

Applicant Must Provide:

- ☒ An ~~initial~~ or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An ~~initial~~ or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support

Technical Assistance.....703-287-0200

To Purchase PatentIn Software.....703-306-2600

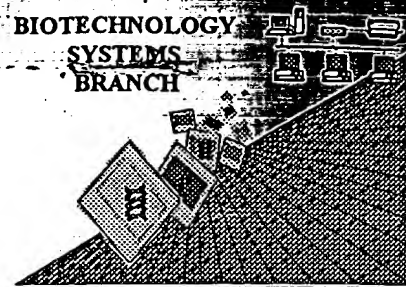
PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

Tuner

RAW SEQUENCE LISTING

ERROR REPORT

BIOTECHNOLOGY
SYSTEMS
BRANCH



The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following CRF diskette:

Application Serial Number:

09/328,877

Art Unit / Team No. :

01/K

Date Processed by STIC:

6/28/99

THE ATTACHED PRINTOUT EXPLAINS THE ERRORS DETECTED.

PLEASE BE SURE TO FORWARD THIS INFORMATION TO THE APPLICANTS BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANTS ALONG WITH A NOTICE TO COMPLY or,
- 2) CALLING APPLICANTS AND FAXING THEM A COPY OF THE PRINTOUT WITH A NOTICE TO COMPLY

THIS WILL INSURE THAT THE NEXT SUBMISSION RECEIVED FROM THEM WILL BE ERROR FREE.

IF YOU HAVE ANY FURTHER QUESTIONS, PLEASE CALL:

MARK SPENCER 703-308-4212

Raw Sequence Listing Error Summary

ERROR DETECTED SUGGESTED CORRECTION

SERIAL NUMBER:

09/328,827

ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE

- 1 Wrapped Nucleics The number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".
- 2 Wrapped Aminos The amino acid number/text at the end of each line "wrapped" down to the next line.
This may occur if your file was retrieved in a word processor after creating it.
Please adjust your right margin to .3, as this will prevent "wrapping".
- 3 Incorrect Line Length The rules require that a line not exceed 72 characters in length. This includes spaces.
- 4 Misaligned Amino Acid The numbering under each 5th amino acid is misaligned. This may be caused by the use of tabs
Numbering between the numbering. It is recommended to delete any tabs and use spacing between the numbers.
- 5 Non-ASCII This file was not saved in ASCII (DOS) text, as required by the Sequence Rules.
Please ensure your subsequent submission is saved in ASCII text so that it can be processed.
- 6 Variable Length Sequence(s) contain n's or Xaa's which represented more than one residue.
As per the rules, each n or Xaa can only represent a single residue.
Please present the maximum number of each residue having variable length and
indicate in the (ix) feature section that some may be missing.
- 7 PatentIn ver. 2.0 "bug" A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid
sequence(s) . Normally, PatentIn would automatically generate this section from the
previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section
to the subsequent amino acid sequence.
- 8 Skipped Sequences Sequence(s) missing. If intentional, please use the following format for each skipped sequence:
(OLD RULES) (2) INFORMATION FOR SEQ ID NO:X:
 (i) SEQUENCE CHARACTERISTICS:(Do not insert any headings under "SEQUENCE CHARACTERISTICS")
 (xi) SEQUENCE DESCRIPTION:SEQ ID NO:X:
 This sequence is intentionally skipped

Please also adjust the "(iii) NUMBER OF SEQUENCES:" response to include the skipped sequence(s).
- 9 Skipped Sequences Sequence(s) missing. If intentional, please use the following format for each skipped sequence.
(NEW RULES) <210> sequence Id number
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- 10 Use of n's or Xaa's Use of n's and/or Xaa's have been detected in the Sequence Listing.
(NEW RULES) Use of <220> to <223> is MANDATORY if n's or Xaa's are present.
In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.
- 11 Use of <213>Organism Sequence(s) are missing this mandatory field or its response.
(NEW RULES)
- 12 Use of <220>Feature Sequence(s) are missing the <220>Feature and associated headings.
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(See "Federal Register," 6/01/98, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of new Rules)
- 13 PatentIn ver. 2.0 "bug" Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted
file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing).
Instead, please use "File Manager" or any other means to copy file to floppy disk.

PAGE: 1

RAW SEQUENCE LISTING
PATENT APPLICATION US/09/328,877

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This Raw Listing contains the General Information
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Does Not Comply
Corrected Diskette Needed

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2      Li, Jinhe
3      Pauley, Adele M.
4      Pharmacia & Upjohn Company
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PAGE: 3

RAW SEQUENCE LISTING
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140 aacctttaaa gggattgtgt ctatggtttg attcacttag aaattttatt ttcttataac 3540
141 ttaagtgcaa taaaatgtgt tttttcatgt t 3571

W-->

Handwritten note: "Handwritten '10' and a large arrow pointing down from line 123 to line 138." The arrow is drawn on the left margin, starting near line 123 and pointing down to line 138.

W-->

142 <210> SEQ ID NO 3
143 <211> LENGTH: 627
144 <212> TYPE: PRT

PAGE: 4

RAW SEQUENCE LISTING
PATENT APPLICATION US/09/328,877DATE: 06/28/1999
TIME: 15:36:58

Input Set: I328877.RAW

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145 <213> ORGANISM: Homo sapiens
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149 Cys Gly Val Leu Leu Pro Val Leu Leu Pro Asn Leu Pro Phe Leu Thr
150 20 25 30
151 Cys Leu Ser Met Ser Thr Leu Glu Ser Val Thr Tyr Leu Pro Glu Lys
152 35 40 45
153 Gly Leu Tyr Cys Gln Arg Leu Pro Ser Ser Arg Thr His Gly Gly Thr
154 50 55 60
155 Glu Ser Leu Lys Gly Lys Asn Thr Glu Asn Met Gly Phe Tyr Gly Thr
156 65 70 75 80
157 Leu Lys Met Ile Phe Tyr Lys Met Lys Arg Lys Leu Asp His Gly Ser
158 85 90 95
159 Glu Val Arg Ser Phe Ser Leu Gly Lys Lys Pro Cys Lys Val Ser Glu
160 100 105 110
161 Tyr Thr Ser Thr Thr Gly Leu Val Pro Cys Ser Ala Thr Pro Thr Thr
162 115 120 125
163 Phe Gly Asp Leu Arg Ala Ala Asn Gly Gln Gly Gln Arg Arg Arg
164 130 135 140
165 Ile Thr Ser Val Gln Pro Thr Gly Leu Gln Glu Trp Leu Lys Met
166 145 150 155 160
167 Phe Gln Ser Trp Ser Gly Pro Glu Lys Leu Leu Ala Leu Asp Glu Leu
168 165 170 175
169 Ile Asp Ser Cys Glu Pro Thr Gln Val Lys His Met Met Gln Val Ile
170 180 185 190
171 Glu Pro Gln Phe Gln Arg Asp Phe Ile Ser Leu Leu Pro Lys Glu Leu
172 195 200 205
173 Ala Leu Tyr Val Leu Ser Phe Leu Glu Pro Lys Asp Leu Leu Gln Ala
174 210 215 220
175 Ala Gln Thr Cys Arg Tyr Trp Arg Ile Leu Ala Glu Asp Asn Leu Leu
176 225 230 235 240
177 Trp Arg Glu Lys Cys Lys Glu Glu Gly Ile Asp Glu Pro Leu His Ile
178 245 250 255
179 Lys Arg Arg Lys Val Ile Lys Pro Gly Phe Ile His Ser Pro Trp Lys
180 260 265 270
181 Ser Ala Tyr Ile Arg Gln His Arg Ile Asp Thr Asn Trp Arg Arg Gly
182 275 280 285
183 Glu Leu Lys Ser Pro Lys Val Leu Lys Gly His Asp Asp His Val Ile
184 290 295 300
185 Thr Cys Leu Gln Phe Cys Gly Asn Arg Ile Val Ser Gly Ser Asp Asp
186 305 310 315 320
187 Asn Thr Leu Lys Val Trp Ser Ala Val Thr Gly Lys Cys Leu Arg Thr
188 325 330 335
189 Leu Val Gly His Thr Gly Gly Val Trp Ser Ser Gln Met Arg Asp Asn
190 340 345 350
191 Ile Ile Ile Ser Gly Ser Thr Asp Arg Thr Leu Lys Val Trp Asn Ala
192 355 360 365
193 Glu Thr Gly Glu Cys Ile His Thr Leu Tyr Gly His Thr Ser Thr Val
194 370 375 380

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PAGE: 5

RAW SEQUENCE LISTING PATENT APPLICATION US/09/328,877

DATE: 06/28/1999
TIME: 15:36:58

Input Set: I328877.RAW

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195 Arg Cys Met His Leu His Glu Lys Arg Val Val Ser Gly Ser Arg Asp
196 385 390 395 400
197 Ala Thr Leu Arg Val Trp Asp Ile Glu Thr Gly Gln Cys Leu His Val
198 405 410 415
199 Leu Met Gly His Val Ala Ala Val Arg Cys Val Gln Tyr Asp Gly Arg
200 420 425 430
201 Arg Val Val Ser Gly Ala Tyr Asp Phe Met Val Lys Val Trp Asp Pro
202 435 440 445
203 Glu Thr Glu Thr Cys Leu His Thr Leu Gln Gly His Thr Asn Arg Val
204 450 455 460
205 Tyr Ser Leu Gln Phe Asp Gly Ile His Val Val Ser Gly Ser Leu Asp
206 465 470 475 480
207 Thr Ser Ile Arg Val Trp Asp Val Glu Thr Gly Asn Cys Ile His Thr
208 485 490 495
209 Leu Thr Gly His Gln Ser Leu Thr Ser Gly Met Glu Leu Lys Asp Asn
210 500 505 510
211 Ile Leu Val Ser Gly Asn Ala Asp Ser Thr Val Lys Ile Trp Asp Ile
212 515 520 525
213 Lys Thr Gly Gln Cys Leu Gln Thr Leu Gln Gly Pro Asn Lys His Gln
214 530 535 540
215 Ser Ala Val Thr Cys Leu Gln Phe Asn Lys Asn Phe Val Ile Thr Ser
216 545 550 555 560
217 Ser Asp Asp Gly Thr Val Lys Leu Trp Asp Leu Lys Thr Gly Glu Phe
218 565 570 575
219 Ile Arg Asn Leu Val Thr Leu Glu Ser Gly Gly Ser Gly Gly Val Val
220 580 585 590
221 Trp Arg Ile Arg Ala Ser Asn Thr Lys Leu Val Cys Ala Val Gly Ser
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225 Asp Met Lys
226 625
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228 <211> LENGTH: 592
229 <212> TYPE: PRT
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235 20 25 30
236 Lys Gly Lys Asn Thr Glu Asn Met Gly Phe Tyr Gly Thr Leu Lys Met
237 35 40 45
238 Ile Phe Tyr Lys Met Lys Arg Lys Leu Asp His Gly Ser Glu Val Arg
239 50 55 60
240 Ser Phe Ser Leu Gly Lys Lys Pro Cys Lys Val Ser Glu Tyr Thr Ser
241 65 70 75 80
242 Thr Thr Gly Leu Val Pro Cys Ser Ala Thr Pro Thr Thr Phe Gly Asp
243 85 90 95
244 Leu Arg Ala Ala Asn Gly Gln Gly Gln Gln Arg Arg Arg Ile Thr Ser

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Input Set: I328877.RAW

Line ? Error/Warning

Original Text

58 W "N" or "Xaa" used: Feature required
73 W "N" or "Xaa" used: Feature required
123 W "N" or "Xaa" used: Feature required
138 W "N" or "Xaa" used: Feature required

gaaaagcttt tttttttatt tttngccaa ccattgcc
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ttgtttttgt acagttatca tgaaaagctt tttttttt
gatctttttt cctccttctg tttatttttt tgnttggt